Serial No.: 10/636,182 Filed: August 7, 2003

For: DRUG DELIVERY DEVICE AND METHOD

Examiner: Gilbert, Andrew M.
Group Art Unit: 3767
Docket No.: AMS0091/US

Remarks

Amendments

Claims 13-16 are pending in the application. Claims 13 and 14 have been amended as shown above. No claims have been added.

Claim 13 has been amended to recite that the drug delivery path preservation means delivers a substance to the drug delivery ports for resisting fibrous occlusion of the ports, and that the drug delivery preservation means is proximate the drug delivery ports. Claim 14 has been amended to correct a punctuation error discovered during preparation of this Response. It is submitted that these amendments do not introduce any new matter, are fully supported by the specification, and place the claims in condition for immediate allowance.

Rejections

The Rejection Under 35 U.S.C. 102(b)

Claims 13, 15 and 16 have been rejected under 35 U.S.C. 102(b) over U. S. Patent 5,041,107 (hereinafter Heil). Applicants traverse these rejections and submit that Heil does not anticipate these claims.

With regard to Heil, the Examiner argues that the Heil reference does not *only* disclose preventing occlusion of the drug delivery ports by a physical barrier. He argues that Heil discloses a plastic membrane bonded to the catheter body; that the membrane is tightly conformed to the body; and that the membrane covers the slits. He further argues that the material of the membrane is chosen so as to have a molecular weight that is a total barrier against high molecular weight blood clot forming substances such as fibrinogen and thrombin. He concludes that this means that the membrane is explicitly disclosed as being a part of the drug delivery port and that the substance for resisting fibrous occlusions is in the port.

Applicants disagree with reasoning and conclusion. The ports of Heil are self-sealing openings in the catheter body. See Figures 1-4. As acknowledged by the Examiner, the protective membrane is attached to the catheter body at two places. See Figure 3. Thus, whatever the characteristics of the plastic film used in Heil are, it still is a plastic film that covers the drug delivery ports and remains a physical barrier to the clot forming substances. Additionally, this plastic film is not "in" the drug delivery ports. To the contrary it is **over**,

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that is above, the ports and cannot be in them. For these reasons alone, the rejection of claims 13, 15 and 16 under 35 U.S.C. 102(b) over Heil cannot be sustained.

Applicants have further clarified the present invention as embodied in claim 13. The claim now states that the drug delivery path preservation means delivers a substance to the drug delivery ports for resisting fibrous occlusion of the ports. Heil does not disclose the delivery of a substance to the drug delivery ports. It only discloses the use of a film to protect the drug delivery ports from a build-up of clot-forming substances by preventing those substances from reaching the ports. Consequently, Heil fails to teach at least one required element of the claimed invention and therefore the rejection of claims 13, 15 and 16 under 35 U.S.C. 102(b) over Heil cannot be sustained for this additional reason.

The Rejection Under 35 U.S.C.103(a)

Claim 14 has been rejected under 35 U.S.C. 103(a) over Heil in view of U. S. Patent 5,520,672 (hereinafter Urry).

As shown above, Heil does not disclose the present invention substantially as claimed. Heil also fails to suggest the replacement of the film with a drug delivery path preservation means that delivers a substance to the drug delivery ports for resisting fibrous occlusion of the ports substance that resists occlusion. Finally, Heil fails to suggest that the substance that resists fibrous occlusion of the drug ports comprises poly(glycine-valine-glycine-valine-proline). Consequently, Heil fails to supply any logic why one should replace the physical barrier with such a substance.

Urry fails to supply any reason to replace the film of Heil with such a substance.

Urry is directed to a super absorbent polymer and uses thereof. Super absorbent polymers have absorbent properties that can switch between a swollen state and a contracted state depending upon the environment in which they are used. These polymers are used to make diapers, sanitary napkins, wound dressings, liners, toilet paper, tampons, antiperspirants, and the like.

Urry does not disclose the use of these materials in connection with a drug delivery catheter. In fact, the use of such polymers would destroy the utility of a catheter by absorbing fluids and causing the catheter to lose its functionality. Thus Urry teaches away from the present invention and provides no motivation to selectively take a portion of its discolsure and combine that portion with Heil. As a result, the combination of Urry with Heil does not support the rejection of claim 14 under 35 U.S.C. 103(a).

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The combination of Urry with Heil fails to support the Examiner's rejection under 35 U.S.C. 103(a) for another reason. The product of this combination would have the same construction as that taught in Heil except that the polymer taught in Heil would be replaced by a solid film of a different material. The film would still be attached at two discrete points on the catheter and would serve as a physical barrier to contact between the drug ports and clot-forming substances. Therefore, the combination of Urry with Heil does not provide what Applicants have claimed and does not support the rejection of claim 14 under 35 U.S.C.

Conclusion

Based on the preceding comments, Applicants submit that they have shown that claims 13-16 are patentable over the cited references. They request reconsideration of the rejections and allowance of all claims.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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